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IN THE

Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE, and TELIOS PHARMACEUTICALS, INC.,

Respondents.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Federal Circuit

MOTION FOR LEAVE TO FILE AND BRIEF FOR *AMICUS CURIAE* ELI LILLY AND COMPANY IN SUPPORT OF PETITIONER

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MOTION OF ELI LILLY AND COMPANY FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER MERCK KGAA

Pursuant to Sup. Ct. Rule 37.2(b), *amicus* - Eli Lilly and Company – moves for leave to file the attached brief *Amicus Curiae* in support of Petitioners seeking review of *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

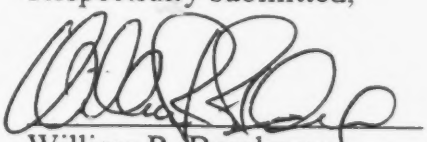
In the decision below, a divided panel of the Federal Circuit ruled that certain pre-clinical development activities that were not "reasonably related to clinical tests for the FDA" were not entitled to the safe harbor exemption to patent infringement provided by 35 U.S.C. §271(e)(1). The extent of the Federal Circuit's holding is unclear, as is what sort of drug development activity is exempt from infringement and what is not. The majority panel's original decision appeared to state that no activity relating to innovative or pioneering drugs would be entitled to the safe

harbor exemption. However, since such a holding would be contrary to established Supreme Court precedent, the majority panel subsequently published an errata sheet to attempt to clarify its holding. Even after the publication of the errata sheet, innovator *and* generic drug companies are left to guess what studies they conduct or data they generate would expose them to claims for patent infringement. Such uncertainty will quell drug development and provide a *de facto* extension of term for certain classes of patents – a result that was considered by this Court to be a "distortion" of the statute and of Congress' intent.

Amicus is a research-based pharmaceutical company that discovers and develops innovative therapeutic and biopharmaceutical products and has recognized expertise in the drug development process. This brief is offered to provide an analysis of the legal error committed by the majority panel, a basic description of the drug development process, and an explanation of the risks that this decision poses to stifling new drug development.

While Respondents did provide verbal consent for *amicus* to file this brief in support of Petitioners, this motion is deemed to be necessary since the deadline for filing is imminent and *amicus* has not yet received written consent as required by the rules.

Respectfully submitted,



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I. INTEREST OF AMICUS CURIAE*

Eli Lilly and Company ("Lilly") is a research-based pharmaceutical company that discovers and develops innovative products and services enabling people to live longer, healthier, and more active lives. If non-clinical development activities associated with the development of new drugs do not fall within the 271(e)(1) exemption, then development of some drugs will be substantially delayed and in some cases may not even occur. A patent covering enabling technology used in the development of a new chemical entity can potentially block drug development, and the patent holder may be unable or unwilling to license the patent or develop a drug on its own. Without sufficient freedom to conduct non-clinical research, development and approval of many new drugs will not occur. Without new drugs, there can be no generic equivalents.

Lilly has no stake in the parties in this litigation or in the result in the case, other than the fundamental interest in the case set out above. The parties to the case have not contributed in any way to the preparation of this *amicus* brief.

Mr. Robert A. Armitage was an expert for Petitioner Merck KgaA, and he is now General Counsel of *Amicus Curiae* Eli Lilly and Company. Mr. Armitage did not contribute to drafting or reviewing this brief.

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* The parties verbally consented to the filing of this brief; but written consent of Respondent was not received in time. Therefore a Motion for Leave to File accompanies this brief. This brief was not authored in whole or in part by counsel for a party, and no person or entity, other than the *amicus curiae* made a monetary contribution to the preparation and submission of this brief.

II. INTRODUCTION

Under the Federal Circuit's holding in this case, non-clinical activity may not be entitled to the Hatch-Waxman safe harbor exemption to patent infringement. This holding is contrary to established Supreme Court and Federal Circuit precedent, and also to the wording and purpose of the statute, which provides that "it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. §271(e)(1).

If the Federal Circuit holding can be construed to exclude non-clinical activity from the ambit of the statute and that a patent can be used to exclude *in vivo* drug testing, the majority has created a conflict with Supreme Court precedent. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990) ("[T]he safe harbor provision covers the "entire statutory scheme of regulation") and its own precedent. *See also AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) ("The statute, therefore, does not look to the underlying purposes or attendant consequences of the activity . . . as long as the use is reasonably related to FDA approval"). It would also be contrary to lower court holdings demonstrating an established standard of practice, including one case affirmed by the Federal Circuit. *See, e.g., Intermedics v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). If antecedent activities that are necessary, though perhaps not usually reportable or reported, are not entitled to the

safe harbor exemption, then drug developers would be prevented from ever getting to protected activities. The Federal Circuit has, in one interpretation of the ruling, gutted the exemption for new drugs. This will have a devastating effect on advances in human medicine and, ironically, the cost of generic drugs, because generic drugs can only exist after a new drug has been created and marketed for a period of time.

The Supreme Court has stated that the privileges bestowed by patents are not unlimited and that the owner's pecuniary interest is weighed in light of public policy. *See Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) ("The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit . . . [and] . . . makes reward to the owner a secondary consideration"). The Federal Circuit's holding has provided a *de facto* extension of Integra's compound and tool patents and delays new drug development and new cures for patients. The Federal Circuit did not consider this resulting harm to patients when it excluded a significant portion of new drug discovery and development activities from the 271(e)(1) safe harbor. These harms are significant and clearly outweigh the interest in a patent right or any pecuniary benefits gained by patentees who have secured a *de facto* extension of their patent terms by enjoining non-clinical development necessary for FDA approval.

III. REASONS FOR GRANTING THE WRIT

A. The Lower Court's Holding Conflicts with Supreme Court Precedent, and with the Plain Meaning of and Purpose for 35 U.S.C. §271(e)(1).

The majority's opinion, despite the errata that attempts to remedy the clear errors in the original opinion, may restrict the protection of 271(e)(1) to generic drug companies, contrary to the Court's precedent and the plain meaning of 35 U.S.C. §271(e)(1). For example, the court states that one of two "reasons" for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("the 1984 Act") was "to ensure that a patentee's rights did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval." *Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 865 (Fed. Cir. 2003) (emphasis added) (calling attention to the Court's decision in *Lilly*). In fact, there is nothing in the Court's opinion in *Lilly* that states or suggests that the 1984 Act was limited to the activities of generic drug companies.

In a similar vein, the majority's opinion also states:

> The meaning of the phrase "reasonably related" . . . is clearer in the context of the role of the 1984 Act in facilitating expedited approval of a generic version of a drug previously approved by the FDA. . . . As discussed above, the express objective of the 1984 Act was to facilitate the immediate entry of safe, effective generic drugs. . . upon expiration of a pioneer

> drug patent. . . . Therefore, the §271(e)(1) safe harbor clearly covers those pre-expiration activities "reasonably related" to acquiring FDA approval of a drug already on the market. . . . The exemption viewed in this context does not endorse an interpretation of §271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market.

Integra, 331 F.3d at 866-67 (emphasis added).

While appearing to retreat from the original opinion's clear message that 271(e)(1) was only available for generic drug company activities, the errata made no substantive change. The Federal Circuit's decision, even as amended, may thus effectively deny any benefit of 271(e)(1) to one not intending to file an ANDA for FDA approval for a drug already on the market.

The majority's opinion in this regard is clearly contrary to the Court's precedent in *Lilly*, to the plain reading of the statute, to the promotion of human health, and even to the facilitation of the availability of generic drugs.

The Court also stated that 271(e)(1) "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Lilly,* 496 U.S. at 671. The Court did not limit the type of competitor to a generic drug competitor. The Court did not either limit the types of infringing activities – all activities necessary to obtain regulatory approval were countenanced by the Court.

In this case, Petitioner Merck's activities were

necessary to obtain regulatory approval. It was necessary in order to obtain regulatory approval to identify a molecule that would most likely be safe and effective in humans. One cannot obtain regulatory approval without first identifying the molecule for which approval is sought. Today, as when Merck carried out its studies, molecules can only be identified by making them and testing them. Such molecules cannot be identified merely by philosophical contemplation or by computerized predictions. Instead, many potential candidates, typically many hundreds or thousands, have to be made and tested in a laboratory before the single molecule that by all measures is the one most likely to be safe and effective in humans is declared to be "the" candidate for clinical studies. This process of trial and error takes many years.

The majority also concluded Merck's activities were not "reasonably related" to the development and submission of information to the FDA because the majority accepted as true the statement that the "Scripps-Merck experiments did not supply information for submission to the United States Food and Drug Administration (FDA)." *Integra*, 331 F.3d at 865-66. However, this statement is erroneous, since the experiments identified the active agent that would have been included in any submission to the FDA. The experiments did indeed supply information for submission to the FDA – the identity of the active agent!

An exemption under 271(e)(1) covering non-clinical activity is appropriate in view of not only the uncertainty of pre-clinical activities and FDA requirements, but also to encourage innovative medical cures, and to prevent extension of patent rights beyond expiration. The majority's evident concern that the exemption not "swallow the whole benefit of the Patent Act for some categories of

biotechnological inventions" does not justify the undermining of the legislative purpose of the statute. *Id.* at 867.

The majority's opinion relies heavily on selected portions of the legislative history that, frankly, cut both ways. However, the legislative history relied upon most heavily by the majority panel conflicts with the Court's own precedent in *Lilly*. For example, the majority comments:

> The House Committee that initiated this provision expressly described the pre-market approval activity as "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." The Committee further characterized the limits of this provision, noting that the "nature of the interference with the rights of the patent holder" would not be "substantial," but "de minimus [sic]." Thus, the 1984 Act was "designed to benefit the makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public."

Id. at 865 (citations omitted).

However, a more pertinent portion of the legislative history of 35 U.S.C. § 271(e)(1) *supports* a construction of the statute that would allow for exempting pre-clinical activities. H.R. REP. NO. 98-957 p. 45 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal

law which regulates the approval of drugs. This section does not permit commercial sale of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredient to such party. The information which can be developed under this provision is the type required to obtain approval of the drug. A party which develops such information, but decides not to submit the application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought).

The Supreme Court has affirmatively stated that the statute applies to more than just generic drugs. The Court stated, "All of the products eligible for a patent term extension under § 201 [§ 156] are subject to § 202 [§ 271(e)(1)], since all of them--medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products--are subject to premarket approval under various provisions of the FDCA . . . ." *Lilly,* 496 U.S. at 674. In considering whether the *de minimis* nature of the infringement mattered the Court stated, "Even if the competitive injury caused by the noninfringement provision is *de minimis* with respect to most drugs, surely it is substantial with respect to some of them -- so the 'serious constitutional question' (if it is that) is not avoided by petitioner's construction either." *Id.* at 679 n.7. The desire to speed new drugs and devices to market trumps the magnitude of the infringement in these types of cases. Thus, the Federal Circuit majority's reasoning and interpretation of the 271(e)(1) exemption is in direct conflict with controlling precedent from the U.S. Supreme Court.

B. Non-Clinical Activities Are Reasonably Related to the Development and Submission of Information Under a Federal Law Which Regulates the Approval of Drugs.

In support of its holding that Merck's sponsored pre-clinical development activities are not exempted from infringement under 35 U.S.C. 271(e)(1), the Federal Circuit states that such activities are "not 'solely for uses reasonably related' to clinical tests for the FDA." *Integra*, 331 F.3d at 866 (emphasis added). This is an erroneous reading of the statute. Rather, 271(e)(1) exempts from infringement uses of "a patented invention . . . reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. 271(e)(1). There is no requirement that the "information under a Federal law" be clinical data. The infringing acts must be "solely" for the exempt use, but, to be exempt, a use need only be "reasonably related" to the stated objective – development and submission of information to the FDA. Such information comprises both clinical and pre-clinical information.

It is well-settled that the phrase "reasonably related" within the context of 271(e)(1) provides latitude for the drug developer to engage in a wide variety of activities in the course of the drug development process.

> We infer that the phrase "reasonably related" . . . as used in §271(e)(1) reflects Congress' acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that

> agency's approval. Thus, Congress used this phrase to communicate its intention that the courts give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA.

Intermedics, 775 F. Supp. at 1280. The test is prospective, in that it evaluates the potential infringer's activities at the time they were undertaken, and objective, in that it does not concern itself with the potential infringer's state of mind. *See Amgen,* 3 F. Supp. 2d 104.

As part of the rationale for its holding, the Federal Circuit characterizes the work performed by Scripps as "general biomedical research to identify new compounds." The Federal Circuit stated the FDA has no interest in the "hunt for drugs" and, thus, the use was not reasonably related to clinical testing.

Since this Court first addressed section 271(e)(1), courts have been reluctant to limit the scope of research and development activities that are "reasonably related" to FDA approval in the manner suggested by the Federal Circuit. *See, e.g., Lilly,* 496 U.S. 661; *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). At the very least, activities to generate information for Investigational New Drug ("IND") submissions must be covered by the exemption. There is a significant amount of pre-clinical information required for approval of an IND, including, most essentially, the identity of the molecule whose safety and efficacy in humans is to be tested. Additionally, the regulations require the applicant to provide information regarding a drug's pharmacological class, a summary of the pharmacokinetic and toxicological

effects in animals or *in vitro*, and any information that would aid in the evaluation of the proposed clinical trials with respect to safety or their design. *See* 21 C.F.R. §§ 312.23(a)(3)(i), 312.23(a)(5)(ii), 312.23(a)(5)(iii), 312.23(a)(10)(iv). Further, the FDA can require "any other relevant information needed for review of the application." 21 C.F.R. § 312.23(a)(11).

The record shows Merck's and Scripp's activities were specifically tailored for IND submission, the purpose of the contract was for conducting late-stage pre-clinical development studies with the intent to enter clinical trials within three years and a limited number of compounds were actually tested during the collaboration. The Federal Circuit does not distinguish between the different types of pre-clinical development activities conducted during development, but simply holds that none of the activities are entitled to the safe harbor. However, the FDA clearly views focused pre-clinical activity as part of the process to obtain marketing approval.

The process begins long before any submission of information to the FDA and is an expensive and risky enterprise. An FDA Consumer Special Report explains this process. In it, the FDA tells the story of new drug development in the United States, stating that "[t]he research process is a complicated, time-consuming and costly one whose end result is never known at the outset." Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, FDA CONSUMER SPECIAL REPORT FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES, Jan. 1995, http://www.fda.gov/fdac/special/newdrug/begin.html. The FDA estimates that this research process averages eight-and-a-half years and includes early laboratory and animal

testing, as well as later clinical trials using human subjects. The FDA breaks out the research process into two major phases – (i) preclinical research, all activities done prior to testing in human subjects, that may help demonstrate safety and efficacy, and (ii) clinical research, the direct testing of safety and efficacy in humans. Results and underlying information relating to both phases of research must be submitted to the FDA for consideration. Only after the FDA is convinced by the weight of the evidence does it approve the commercial sale of a pharmaceutical for the treatment of specific disorders.

If the exemption covers only clinical activity, the Federal Circuit panel undercuts and delays not just innovative drug development, but restricts certain aspects of generic drug development and drugs developed under 21 U.S.C. § 355(b)(2) ("505(b)(2)") that the Supreme Court has already suggested is exempt from infringement. *Lilly*, 496 U.S. at 570. For example, in confirming that the 271(e)(1) exemption applies to both ANDA and 505(b)(2) applicants, the Supreme Court implies that even the pre-clinical development work that may be required of a 505(b)(2) applicant or a generic drug falling under 21 U.S.C. § 355(j)(2)(C) would benefit from the safe harbor. If the Federal Circuit indeed holds that no type of pre-clinical testing is exempt from infringement under 271(e)(1), then any time a generic drug applicant is required to conduct pre-clinical tests to support an approval of its ANDA or 505(b)(2) application, then those pre-clinical tests will not be exempt from an infringement claim. While it is probably not the intent of the Federal Circuit to expose these applicants to infringement, there is no rational basis to apply the exemption to ANDA and 505(b)(2) applicants when the same sort of information is not exempt when filed in support of an IND or a new drug

application filed under 21 U.S.C. §355(b)(1). However, if the Federal Circuit's holding is to be interpreted in a consistent way, then it runs counter to Supreme Court precedent as set forth in *Lilly* as well as Congressional intent.

A goal in enacting 35 U.S.C. § 271(e)(1) was to enable competitive products to reach the marketplace as early as possible. H.R. REP. NO. 98-957 p. 15. Allowing pioneering drug companies to operate under this provision for all activities related to new drug approval, both pre-clinical and clinical, is consistent with this goal.

C. The Lower Court's Decision Effects a *de facto* Extension of Patent Term – Precisely What Congress Intended to Prevent by Enacting 35 U.S.C. § 271(e)(1).

There was a day when rigid patent enforcement prevented the initiation by competitors of any activities required to obtain FDA approval until the patent expired. The effect of such rigid patent enforcement was to delay the launch of competing products for the time it took a competitor to carry out its pre-clinical and clinical work, prepare and file its drug application, and receive FDA approval. The delay was typically measured in years. The delay effectively extended the marketing exclusivity of the patent holder, and this was perceived an improper, *de facto* extension of the term of the patent right.

However, this regime of rigid patent enforcement was interred by the 1984 Act, and its resurrection has been thwarted by subsequent judicial rulings, until the Federal Circuit's in *Integra*. The Federal Circuit held that Petitioner Merck's pre-clinical activities, carried out to

identify which molecule would be taken forward for clinical testing, were not protected under 35 U.S.C. §271(e)(1). *Integra*, 331 F.3d at 872.

The effect of the majority's opinion is a *de facto* extension of the term of some patents. Consider, for example, a patent covering a protein product that has already been approved and is on the market. A broad genus claim covering the protein may very well contain proteins having improved properties. (The same situation could arise for non-protein drugs.) Yet, under one interpretation of the majority's rule, no activities directed toward discovering an improved drug that is covered by the patent may be carried out until after the patent expires.

If the initiation of discovery begins only after the patent expires, then a product utilizing an improved protein could not be launched for many years after patent expiry (at least five years and more likely seven to ten years or more, considering the time it takes to discover an improved molecule suitable to be a drug candidate, to conduct pre-clinical and clinical studies, and to receive FDA approval). Under these circumstances, the patentee's product will be effectively free from competition from a competing, improved product for a period of five to ten years or more – a *de facto* extension of the original drug's patent.

The Court characterized such a *de facto* extension of patent term as a "distortion" and recognized that Congress expressly intended to eliminate that distortion through enactment of 271(e)(1). *Lilly*, 496 US at 670-71. The only way to accomplish Congress' purpose of eliminating *de facto* patent extensions is to not draw artificial lines, as the Federal Circuit majority has done, between generic and non-generic activities, between pre-clinical and clinical

activities, and between discovery and post-discovery activities.

D. The Lower Court's Decision Will Delay or Prevent the Discovery and Development of Innovative Therapies, and Thereby Also Delay or Prevent Subsequent Generic Equivalents.

The Supreme Court stated, "The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit . . . [and] . . . makes reward to the owner a secondary consideration". *Sony,* 464 U.S. at 429. The public is best served when there is increased and speedy access to new drugs. This is especially true in areas where there are clearly unmet medical needs such as with AIDS, Alzheimer's disease, and aggressive malignant cancers.

If both pre-clinical and clinical activities for new drugs do not fall within the 271(e)(1) safe harbor, patients will be deprived of timely access to many life-saving innovative products. Forcing lengthy negotiations and expensive licenses early in the new drug process before even understanding whether a drug has a desirable activity, let alone whether it is safe and efficacious in the clinic, will result in decisions not to pursue many of these products. This is especially true given that only 1 in 10000 compounds ever make it to the market.

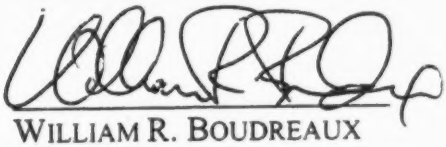
This is a significant risk when a patent holder, possibly a direct competitor, is unwilling to license basic enabling technology. In such a case, the drug developer must wait until patent expiration to initiate development activities. This inhibits innovation and could, in some cases, delay

launch of life-saving medicines up to twenty years. It likewise will delay in some cases the entry of equivalent and more generally affordable generic products. This runs counter to Congressional intent and harms the public's interest in the swift provision of innovative, improved, safe, and effective therapies.

CONCLUSION

For the foregoing reasons, *amicus curiae* Eli Lilly and Company respectfully requests that the Court grant *certiorari*.

Respectfully submitted,



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